Remarks/Arguments

Claims 1 to 19 and 21 to 37, as amended, are pending in the application for the Examiner's review and reconsideration. Applicants present the following remarks to address the concerns expressed in the final Office Action dated December 14, 2006.

Claim Amendments:

Claim 1 has been amended to recite an x-ray diffraction diagram consisting essentially of a major reflection at about 17.2° ± 0.2° 2θ. This amendment is supported on page 4, lines 13-14 of the specification and in figure 1.

Claim 19 has been amended to incorporate the recitations of claim 20. This amendment is supported on page 5, line 30 to page 6, line 2 of the specification. Claim 20 has been cancelled.

Claim 26 has been amended to recite slurrying for less than about 2 hours. This amendment is supported on page 11, lines 17-22 of the specification.

Claims 3, 5, 6, 7, 9, 10, 12, 14, 15, 16, 17, 22, 24, 25, 26, 28, 29, 30, 32, and 34 have been amended for clarity and consistency, as well as to correct minor typographical errors. No new matter has been added to the claims by these amendments.

Claims 9, 27, 29, 30, 31, 33, 35, 36, and 37 have been amended to replace references to "gatifloxacin form __" with characteristic x-ray diffraction data for each of the crystalline forms. In claim 9, "gatifloxacin form T1RP" has been replaced with "a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 12.5°, 20.0°, 20.9°, 22.2°, 24.5°, 25.1°, and 28.0° ± 0.2° 2θ." This amendment is supported by figure 2 of U.S. patent No. 6,413,969 ("'969 patent"), which Applicants' specification describes as disclosing several crystalline forms of gatifloxacin. *See* Specification, p. 4, ll. 4-11; p. 7, ll. 10-12, 15-16. In claims 9, 36, and 37, "gatifloxacin form T1" has been replaced with "a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 7.4°, 8.9°, 9.6°, 11.4°, 12.2°, 12.9°, 14.1°, 16.7°, 21.2°, 21.8°, 24.1°, and 26.0° ± 0.2° 2θ." This amendment is supported on page 5, lines 22-24 of the specification. In claims 27, 36, and 37, "gatifloxacin form P" has been replaced with "a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 11.1°, 11.7°, 12.5° and 23.0° ± 0.2° 2θ." This amendment is supported on page 5, lines 1-3 of the specification. In claims 29 and 33, "gatifloxacin form omega" has been replaced with "a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having

reflections at about 13.5°, 19.6°, 20.4°, 23.6°, 25.8°, and 28.5° ± 0.2° 2θ." This amendment is supported by figure 2 of the '969 patent, which Applicants' specification describes as disclosing gatifloxacin form omega. *See* Specification, p. 7, ll. 10-12. In claim 31, "gatifloxacin form J" has been replaced with "a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 6.7°, 11.3°, 13.8°, and 16.4° ± 0.2° 2θ." This amendment is supported on page 7, lines 17-19 of the specification. In claims 33 and 37, "gatifloxacin form L" has been replaced with "a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having a reflection of strongest intensity at about 17.2° ± 0.2° 2θ." This amendment is supported on page 4, lines 13-14 of the specification and in figure 1. In claims 35 and 37, "gatifloxacin form M" has been replaced with "a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 8.8°, 14.1°, 17.6°, 18.2°, 22.0°, and 22.6° ± 0.2° 2θ." This amendment is supported on page 4, lines 24-26 of the specification. In claim 37, "gatifloxacin form Q" has been replaced with "a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 6.8°, 7.1°, 11.1°, 15.5°, and 17.4° ± 0.2° 2θ." This amendment is supported on page 5, lines 11-13 of the specification. In claim 37, "gatifloxacin form S" has been replaced with "a crystalline form of gatifloxacin characterized by an x-ray diffraction diagram having reflections at about 9.3°, 11.0°, 12.0°, 14.5°, 18.6° and 21.2° ± 0.2° 2θ." This amendment is supported on page 5, line 30 to page 6, line 2 of the specification.

Claim Rejections – 35 U.S.C. § 102(b):

Claims 1, 2, 7, 8, 10, 11, 15, 16, 19, 20, 21, and 24 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,880,283 ("'283 patent"). This rejection has been rendered moot as to claim 20 by the cancellation of the claim. As to the remaining claims, Applicants respectfully traverse.

To anticipate a claim, a single reference must disclose the claimed invention with sufficient clarity to prove its existence in the prior art, and must disclose every element of the challenged claim. *Motorola Inc. v. Interdigital Technology Corp.*, 43 USPQ2d 1481, 1490 (Fed. Cir. 1997); *PPG Industries Inc. v. Guardian Industries Corp.*, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996). Absence from the reference of any claimed element negates anticipation. *Kloster Speedsteel AB v. Crucible Inc.*, 231 U.S.P.Q. 160 (Fed. Cir. 1986). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . .

claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). An anticipatory reference must also enable one of ordinary skill in the art as to the claimed subject matter.

Further, the Board of Patent Appeals and Interferences has held it improper to reject claims to a novel crystalline form of a compound as anticipated solely based upon the prior art disclosure of the compound *per se*. For example, in the unpublished decision of *Ex parte Havens*, the Board reversed a rejection of claims to novel crystalline forms S and T of delavaridine mesylate as anticipated by the prior art disclosure of delavaridine mesylate *per se*, concluding that "to anticipate the claims, the prior art must disclose delavaridine mesylate in the S and T crystal forms." *Ex parte Havens*, Appeal No. 2001-0091, 2003 WL 21279863, *2 (Bd. Pat. App. & Interf.) (a copy of which is attached hereto as "Attachment A" for the Examiner's convenience).

The '283 patent discloses a crystalline gatifloxacin sesquihydrate having a particular powder X-ray diffraction ("PXRD") pattern. '283 patent, col. 2, ll. 22-25; figure 5. The '283 patent also discloses the powder X-ray diffraction pattern of a comparative material. *Id.* at figure 6.

The Office has failed to make out a *prima facie* case of anticipation of the recited crystalline forms of gatifloxacin because, by the Office's own admission, the PXRD patterns of the crystalline forms disclosed in the '283 patent do not contain each and every characteristic of those recited in the claims.

> Matsumoto [the '283 patent] does not disclose the specific gatifloxacin characterized by different x-ray powder diffraction patterns having different diffraction angles, however, one skilled in the art would find the differences in the teaching to be negligible.

Office Action, p. 5.

Nevertheless, Applicants present the following arguments in support of the novelty of the claims.

Claims 1 and 2 recite a crystalline form of gatifloxacin (designated as Form L) characterized by a PXRD pattern consisting essentially of a major reflection at about 17.2° ± 0.2° 2θ. Neither of the PXRD patterns disclosed by the '283 patent consists essentially of a major reflection at 17.2° ± 0.2° 2θ, as recited in the claims. Rather, as illustrated below the PXRD pattern depicted in figure 5 of the '283 patent contains a major reflection at

approximately 8.5° 2θ and the PXRD pattern depicted in figure 6 of the '283 patent contains a major reflection at approximately 21.2° 2θ.

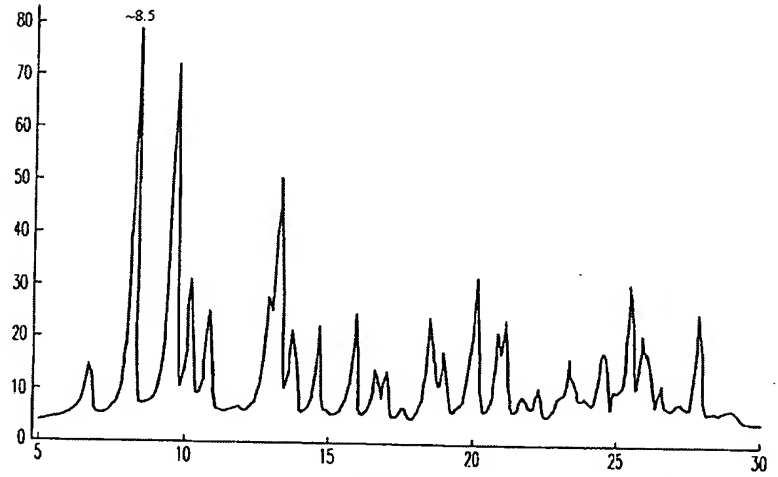

FIG. 5

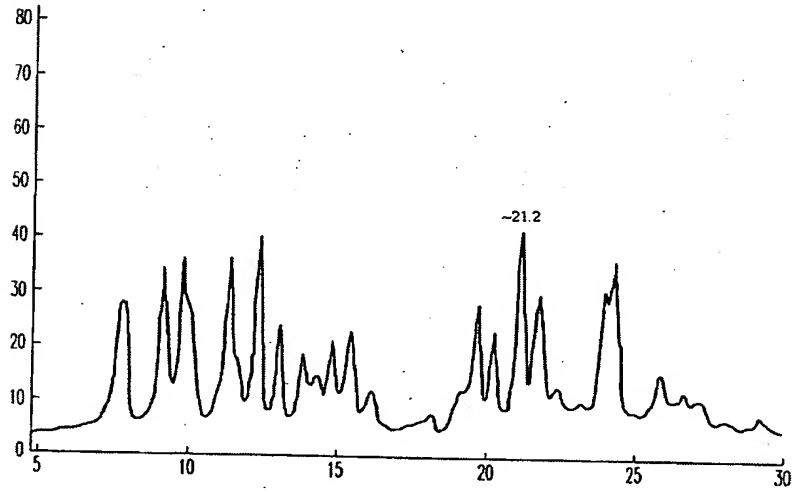

FIG. 6

In view of at least this difference in the PXRD patterns, it is clear that the '283 patent does not disclose Applicants' recited crystalline gatifloxacin Form L. Thus, the legal standard for anticipation under 35 U.S.C. § 102(b) has not been satisfied. *See Havens, supra.*

Claims 7 and 8 recite a crystalline form of gatifloxacin (designated Form M) characterized by a PXRD pattern having reflections at about 8.8°, 14.1°, 17.6°, 18.2°, 22.0°, and 22.6° ± 0.2° 2θ. As illustrated below, neither of the PXRD patterns disclosed by the '283 patent has a pair of reflections at 22.0° and 22.6° ± 0.2° 2θ, as recited in the claims.

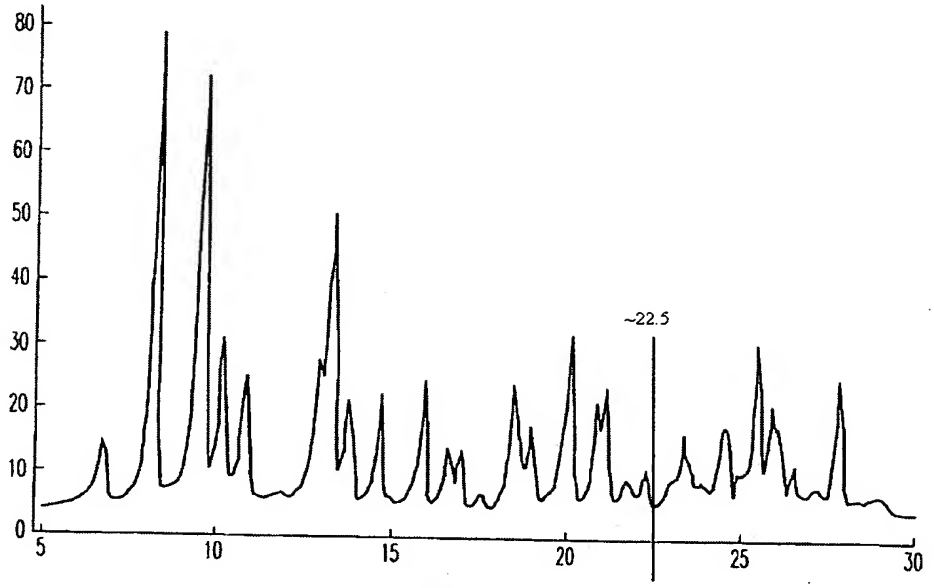

FIG. 5

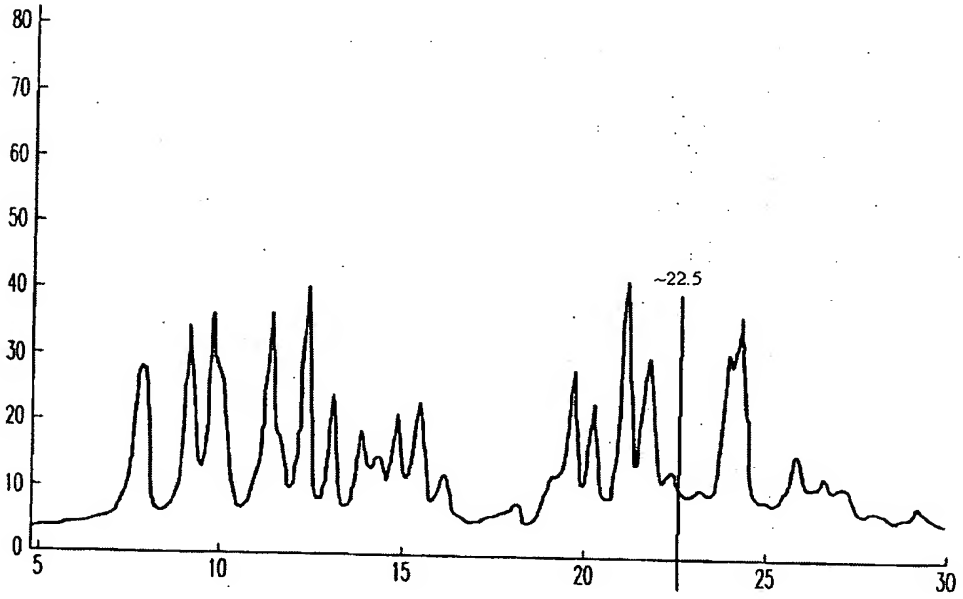

FIG. 6

In view of at least this difference in the PXRD patterns, it is clear that the '283 patent does not disclose Applicants' recited crystalline gatifloxacin Form M. Thus, the legal standard for anticipation under 35 U.S.C. § 102(b) has not been satisfied. *See Havens, supra.*

Claims 10 and 11 recite a crystalline form of gatifloxacin (designated Form P) characterized by a PXRD pattern having reflections at about 11.1°, 11.7°, 12.5°, and 23.0° ± 0.2° 2θ. As illustrated below, neither of the PXRD patterns disclosed by the '283 patent has a pair of reflections at 11.1° and 11.7° ± 0.2° 2θ, as recited in the claims.

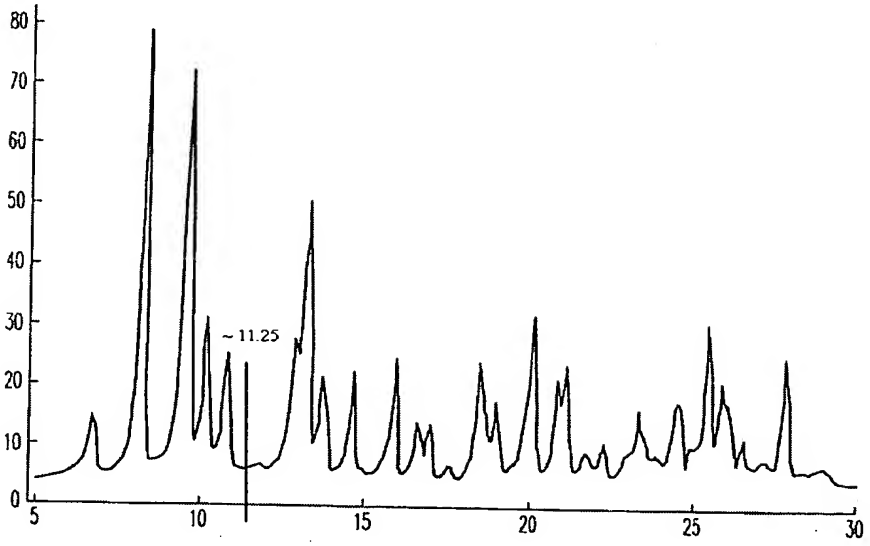

FIG. 5

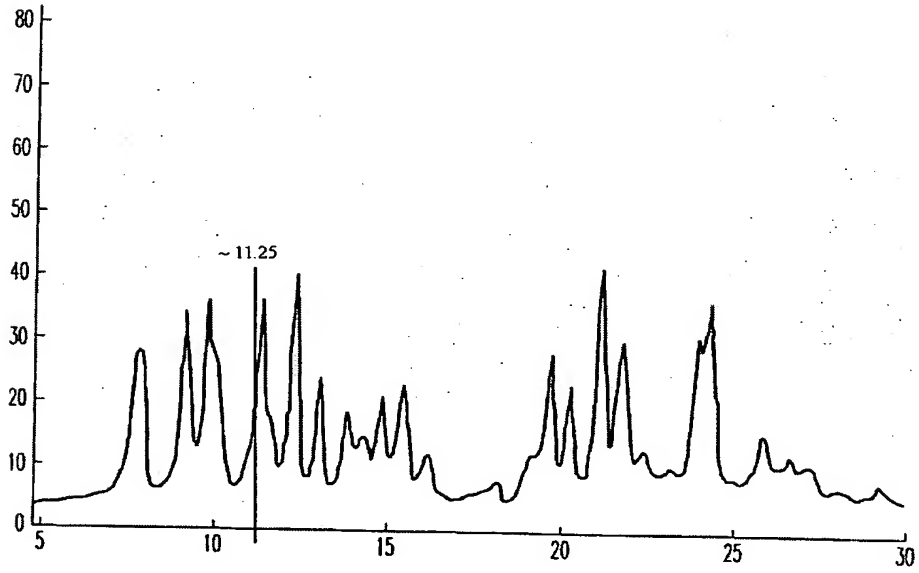

FIG. 6

In view of at least this difference in the PXRD patterns, it is clear that the '283 patent does not disclose Applicants' recited crystalline gatifloxacin Form P. Thus, the legal standard for anticipation under 35 U.S.C. § 102(b) has not been satisfied. *See Havens, supra.*

Claims 15 and 16 recite a crystalline form of gatifloxacin (designated Form Q) characterized by a PXRD pattern having reflections at about 6.8°, 7.1°, 11.1°, 15.5°, and 17.4° ± 0.2° 2θ. As illustrated below, neither of the PXRD patterns disclosed by the '283 patent has a pair of reflections at 6.8° and 7.1° ± 0.2° 2θ, as recited in the claims.

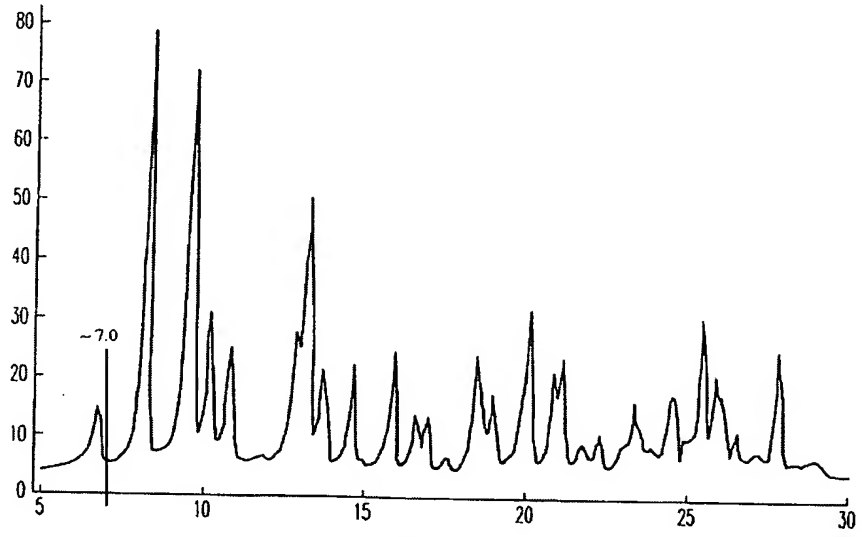

FIG. 5

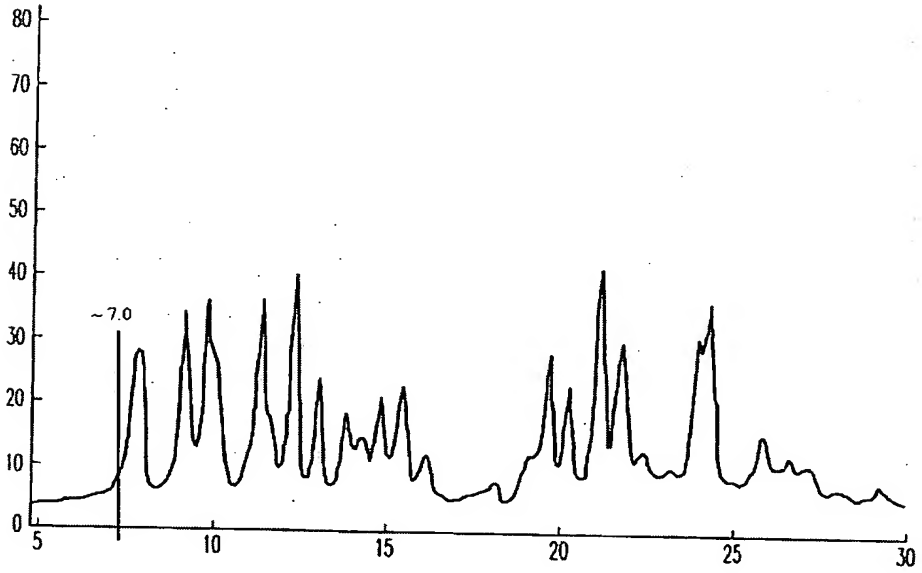

FIG. 6

In view of at least this difference in the PXRD patterns, it is clear that the '283 patent does not disclose Applicants' recited crystalline gatifloxacin Form Q. Thus, the legal standard for anticipation under 35 U.S.C. § 102(b) has not been satisfied. *See Havens, supra.*

Claims 19 and 21 recite a crystalline form of gatifloxacin (designated Form S) characterized by a PXRD pattern having reflections at about 9.3°, 11.0°, 12.0°, 14.5°, 18.6° and 21.2° ± 0.2° 2θ. As illustrated below, the PXRD pattern disclosed in figure 5 of the '283 patent does not have a reflection at 12.0° ± 0.2° 2θ, and the PXRD pattern disclosed in figure 6 of the '283 patent does not have a reflection at 11.0° ± 0.2° 2θ, as recited in the claims.

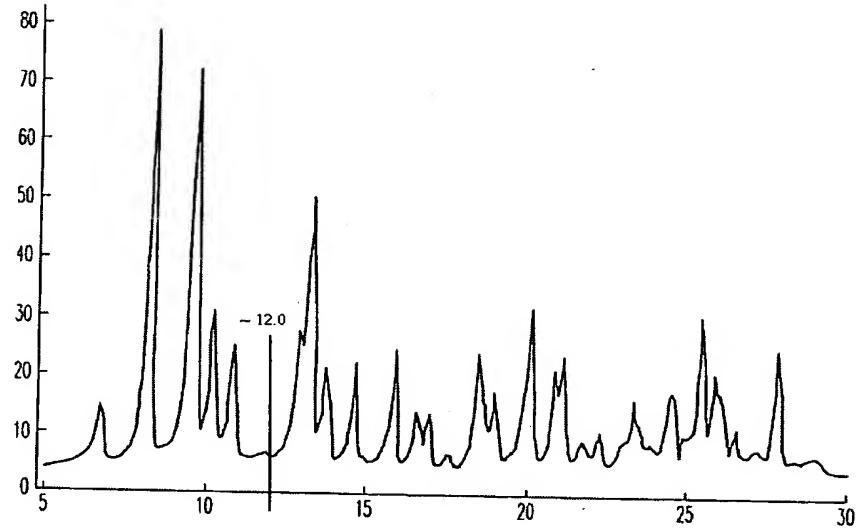

FIG. 5

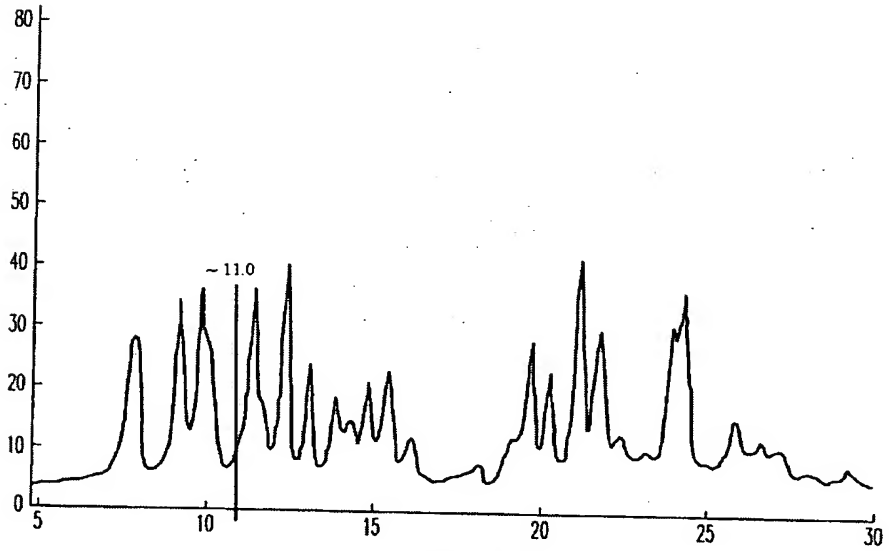

FIG. 6

In view of at least these differences in the PXRD patterns, it is clear that the '283 patent does not disclose Applicants' recited crystalline gatifloxacin Form S. Thus, the legal standard for anticipation under 35 U.S.C. § 102(b) has not been satisfied. *See Havens, supra.*

Claim 24 recites a crystalline form of gatifloxacin (designated Form T1) characterized by a PXRD pattern having reflections at about 7.4°, 8.9°, 9.6°, 11.4°, 12.2°, 12.9°, 14.1°, 16.7°, 21.2°, 21.8°, 24.1°, and 26.0° ± 0.2° 2θ. As illustrated below, the PXRD pattern disclosed in figure 5 of the '283 patent does not have a reflection at 7.4° ± 0.2° 2θ, and the

PXRD pattern disclosed in figure 6 of the '283 patent does not have a reflection at 16.7° ± 0.2° 2θ, as recited in the claim.

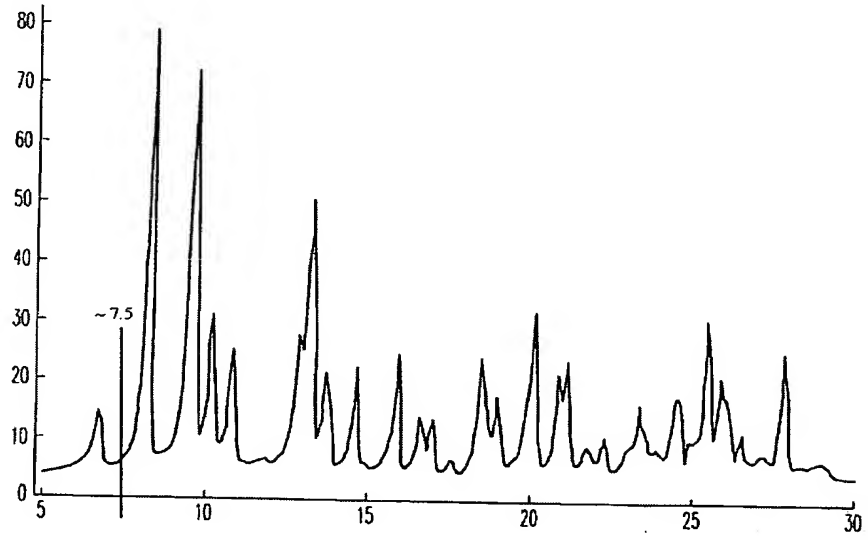

FIG. 5

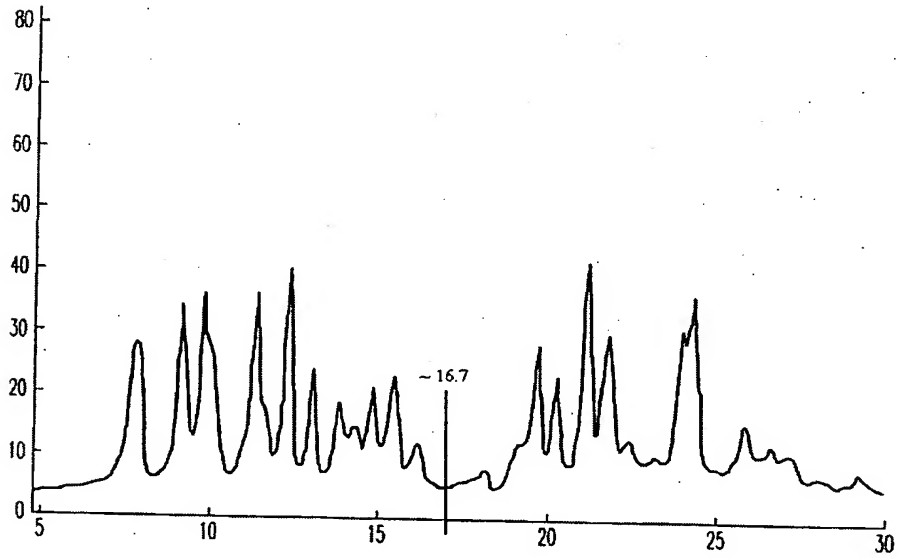

FIG. 6

In view of at least these differences in the PXRD patterns, it is clear that the '283 patent does not disclose Applicants' recited crystalline gatifloxacin Form T1. Thus, the legal standard for anticipation under 35 U.S.C. § 102(b) has not been satisfied. *See Havens, supra.*

Based upon the foregoing arguments, the rejection of claims 1, 2, 7, 8, 10, 11, 15, 16, 19, 20, 21, and 24 under 35 U.S.C. § 102(b) as anticipated by the '283 patent cannot stand and should be withdrawn.

Claim Rejections – 35 U.S.C. § 103:

Claims 1, 2, 7, 8, 10, 11, 15, 16, 19, 20, 21, and 24 also stand rejected under 35 U.S.C. § 103 as allegedly obvious in view of the '283 patent. The rejection has been rendered moot as to claim 20 by the cancellation of the claim. As to the remaining claims, Applicants respectfully traverse.

The U.S. Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. __, 127 S. Ct. 1727, 1740-41 (2007) recently addressed the proper mechanics of an obviousness rejection, stating that in determining motivation to arrive at a claimed invention with a reasonable expectation of the success:

> [I]t will often be necessary to look to interrelated teachings of multiple patents; to the effect of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit.

The Office rejects the claims as obvious in view of the '283 patent based upon the conclusion that "[o]ne of ordinary skill in the art would be motivated to make the claimed compounds in searching for new gatifloxacin forms." Office Action, p. 5.

However, in view of the U.S. Supreme Court's decision in *KSR*, as well as the decisions cited below, this fact alone is not legally sufficient to establish that the crystalline forms of gatifloxacin recited in the claims are *prima facie* obvious in view of the '283 patent.

In order to render a new form of a compound obvious, the prior art must do more than merely suggest its existence.

> [T]o have a reasonable expectation of success, one must be motivated to do more than merely to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.

Pfizer v. Apotex, 480 F.3d 1348, 1365 (Fed. Cir. 2007).

Applying the *Pfizer* reasoning, the Federal Circuit, its predecessor Court of Customs and Patent Appeals, and the Board of Patent Appeals and Interferences have consistently held that in order for a claim to new form of a known compound to be *prima facie* obvious, the prior art must both provide some guidance as to the new form of the compound and provide some guidance as to a process for preparing the new form of the compound, such as discussed in *In re Hoeksema*, 399 F.2d 269 (C.C.P.A. 1968).

The Court of Customs and Patent Appeals in *In re Hoeksema* reversed the Office's rejection of an N-psicofuranoside as obvious in view of the prior art disclosure of a structurally similar homolog of the compound, concluding that "if the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in possession of the public" and, thus, "the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on close relationships between their structures and those of the prior art compounds." *Id.* at 274. The Federal Circuit reiterated this position more recently in *In re Kumar*, 418 F.3d 1361 (Fed. Cir. 2005), reversing the Office's rejection of claims directed to aluminum oxide particles having a particular particle size distribution as obvious in view of a prior art disclosure of aluminum oxide particles. The reference was silent as to the particle size distribution. The Federal Circuit reversed the Office's obviousness rejection in part because the Office had not established that the prior art would have enabled one of skill in the art to produce aluminum oxide particles with the claimed particle size distribution. *See also* M.P.E.P. § 2144.09 (August 2006).

Over the past decade, the Board has repeatedly reversed § 103 rejections of claims to new polymorphic forms of known compounds, applying the principles established by the Court of Customs and Patent Appeals in *Hoeksema*. For example, in *Ex parte Gala*, Appeal No. 2001-0987, 2002 WL 851814, *3 (Bd. Pat. App. & Interf.) (attached hereto as "Attachment B"), the Board reversed an examiner's rejection of claims to loratadine polymorphic form 2 as *per se* obvious over the prior art disclosure of loratadine polymorphic form 1. Unconvinced by the examiner's reasoning, the Board held that the rejection was improper because "the examiner...has not adequately established that the prior art (1) suggests the polymorph form 2 of loratadine; or (2) discloses or renders obvious a method for making the polymorph form 2 of loratadine." The Board has also followed the reasoning set forth in *Gala* in several unpublished decisions.[1]

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[1] *See also Ex parte Havens, supra* (reversing a § 103 rejection of claims to delaviridine mesylate in the S and T crystal forms in view of the prior disclosure of delvaridine mesylate itself because the examiner had "provided no evidence or convincing reasoning why the prior art disclosure of delavirdine mesylate in an undefined state would have suggested the specific S and T crystal forms that are the subject of the instant claims"); *Ex parte Meisel*, Appeal No. 2002-0438, 2002 WL 32334598 (Bd. Pat. App. & Interf. October 10, 2002) (attached hereto as "Attachment C") (reversing a rejection of claims to polymorphs of a known compound as obvious in view of the prior art disclosure of the compound itself because the prior art did not teach or suggest that the compound had different crystalline structures); *Ex parte Polniaszek*, Appeal No. 2001-1805, 2003 WL 22282265 (Bd. Pat. App. & Interf.) (attached hereto as "Attachment D") (reversing a similar rejection (continued...)

As discussed above, the '283 patent does not teach gatifloxacin in any of the crystalline forms L, M, P, Q, S, or T1 recited in the claims. Further, for the reasons discussed below, the '283 patent does not disclose or render obvious a method for making gatifloxacin in any of these crystalline forms.

The '283 patent discloses a process for preparing the crystalline gatifloxacin sesquihydrate by suspending gatifloxacin in water, stirring the suspension for 10 minutes at a temperature of 80°C to 85°C, and recovering the crystalline gatifloxacin sesquihydrate from the suspension by hot filtration. '283 patent, col. 3, ll. 7-22 (example 1).

Applicants have prepared crystalline gatifloxacin forms L, P, and Q by crystallization from solution in methanol/water, ethanol/water, and acetonitrile/water, respectively. In order to obtain crystalline gatifloxacin forms L, P, or Q, one of ordinary skill in the art would have to ignore the teachings of the '283 patent, which discloses the recovery of gatifloxacin from a suspension, rather than from a solution. Further, one of ordinary skill in the art would have to disregard the solvent (water) disclosed in the '283 patent and instead choose to use mixtures of water and methanol, ethanol, or acetonitrile. The '283 patent does not provide any guidance to make such modifications.

Applicants have prepared crystalline gatifloxacin Form M by slurrying crystalline gatifloxacin form T1RP or T1 in methanol. Again, in order to obtain crystalline gatifloxacin Form M, one of ordinary skill in the art would have to disregard the solvent disclosed in the '283 patent and instead choose to use methanol without any guidance to do so. Further, one of ordinary skill in the art would have to choose to use crystalline gatifloxacin Form T1RP or T1 as the starting material. The '283 patent does not provide any guidance that would lead one of ordinary skill in the art to modify the crystalline form of the starting material at all, let alone choose to use the specific Forms T1RP or T1. In fact, crystalline gatifloxacin Form T1 was not even known to exist at the time of the invention.

Applicants have prepared crystalline gatifloxacin Form T1 by crystallizing gatifloxacin from acetonitrile, isolating the crystalline gatifloxacin, slurrying the isolated crystalline gatifloxacin in ethanol for less than about 2 hours, and isolating the gatifloxacin Form T1 from the slurry. Applicants have prepared crystalline gatifloxacin Form S by crystallizing gatifloxacin from acetonitrile, isolating the crystalline gatifloxacin, slurrying the

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of claims to polymorphic forms of a known compound and stating that "we wish to make it clear that 'reliance on per se rules of obviousness is legally incorrect'").

isolated crystalline gatifloxacin in a lower alkanol for at least about 2 hours, and isolating the gatifloxacin Form S from the slurry. In order to obtain crystalline gatifloxacin Form T1 or S, one of ordinary skill in the art would have to disregard the solvent in the '283 patent and instead choose to use a lower alkanol without any guidance to do so. Further, one of ordinary skill in the art would have to choose to maintain the slurry for less than about 2 hours in order to obtain Form T1 or at least about 2 hours in order to obtain Form S. The '283 patent does not provide any guidance to make such modifications.

For these reasons, the '283 patent neither discloses nor renders obvious any process for preparing the recited crystalline forms of gatifloxacin. In fact, the novelty and non-obviousness of Applicants' processes for preparing the recited crystalline forms of gatifloxacin was admitted by the Office in recognizing the allowability of process claims 3, 4, 5, 6, 9, 12, 13, 14, 17, 18, 22, 23, 28, 30, 32, and 34.

Because the '283 patent does not provide any guidance as to the recited crystalline forms of gatifloxacin or enable one of ordinary skill in the art to obtain the recited crystalline forms of gatifloxacin, the rejection of claims 1, 2, 7, 8, 10, 11, 15, 16, 19, 20, 21, and 24 under 35 U.S.C. § 103 as obvious in view of the '283 patent cannot stand and should be withdrawn.

Claim Rejections – 35 U.S.C. § 112, second paragraph:

Claims 2, 8, 9, 11, 16, 21, 25, 26, 27, 29, 31, 33, 35, 36, and 37 stand rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite. Applicants respectfully traverse.

"Determining whether a claim is definite requires an analysis of whether one skilled in the art would understand the bounds of the claim when read in light of the specification." *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1378 (Fed. Cir. 2000) (citing *Personalized Media Comm., LLC v. ITC*, 161 F.3d 696, 705 (Fed. Cir. 1998)). When the specification states the meaning that a term in the claim is intended to have, the claim is examined using that meaning. *In re Zletz*, 893 F.2d 319 (Fed. Cir. 1989); M.P.E.P. § 2173.05(a). "If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more." *Personalized Media Comm.*, 161 F.3d at 705, 48 U.S.P.Q.2d 1180 (citing *Miles Lab., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993). In other words, the definiteness of the claim language must be analyzed, not in a vacuum, but in light of the teachings of the prior art and of the particular application

disclosure as it would be interpreted by one of ordinary skill in the pertinent art. *Solomon*, 216 F.3d at 1378 (citing *In re Moore*, 439 F.2d 1232 (C.C.P.A. 1971)).

The Office alleges that claims 2, 8, 11, 16, 21, and 25 are indefinite because they refer to a figure. Office Action, p. 4. Incorporation of a figure into a claim by reference, however, is appropriate "where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim." M.P.E.P. § 2173.05(s) (August 2006); *In re Fressola*, 27 U.S.P.Q.2d 1608 (Bd. Pat. App. & Interf. 1993). In this case, it is not practical for Applicants to describe in words the x-ray diffraction diagrams in as detailed a form as they appear in the figures, including peak positions, intensities, and shapes, among other details. As such, it is both more comprehensive and concise to incorporate the Figures 1 to 6 by reference into the claims than to attempt to describe all of the intricacies of the x-ray diffraction diagrams in words. Thus, the incorporation by reference of Figures 1 to 6 into claims 2, 8, 11, 16, 21, and 25, respectively, is permissible and does not render the claims indefinite.

The Office alleges that claims 9, 26, 27, 29, 31, 33, 35, 36, and 37 are indefinite because they refer to formulas that are outside the claim. Office Action, p. 4. In response, Applicants have replaced the references to "gatifloxacin form __" in claims 9, 26, 27, 29, 33, 35, 36, and 37 with characteristic x-ray diffraction data for each of the recited crystalline forms. As to claims 29-32, one of ordinary skill in the art would have been familiar with gatifloxacin form K at the time of the invention. Thus, the claims no longer refer to data outside the claims and the rejection is moot.

Based upon the foregoing arguments, the rejection of claims 2, 8, 9, 11, 16, 21, 25, 26, 27, 29, 31, 33, 35, 36, and 37 under 35 U.S.C. § 112, second paragraph as allegedly indefinite cannot stand and should be withdrawn.

Claims 18, 28, 30, 32, and 34 stand rejected under 35 U.S.C. § 112, second paragraph because they depend from allegedly indefinite claims. Applicants respectfully traverse. Because claims 2, 8, 9, 11, 16, 21, 25, 26, 27, 29, 31, 33, 35, 36, and 37 are definite for the reasons discussed above, this rejection should be withdrawn.

Claim Objections:

Claims 3, 4, 5, 6, 9, 12, 13, 14, 17, 18, 22, 23, 28, 30, 32, and 34 stand objected to for depending on a rejected base claim. Applicants respectfully request that the Office remove these objections once the base claims are found allowable.

Conclusion:

In view of the foregoing amendments and remarks, Applicants respectfully submit that the present application is in condition for allowance. Early and favorable action by the Examiner is earnestly solicited. If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same. No fee is believed to be due for the submission of this response. Should any fees be required, please charge such fees to Kenyon & Kenyon, LLP Deposit Account No. 11-0600.

Respectfully submitted,

KENYON & KENYON LLP

Dated: December 27, 2007

By: Gina R. Gencarelli
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ATTACHMENT A

2003 WL 21279863 (Bd.Pat.App & Interf.)
(Cite as: 2003 WL 21279863 (Bd.Pat.App & Interf.))

*1 THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

Board of Patent Appeals and Interferences

Patent and Trademark Office (P.T.O.)
EX PARTE JEFFREY L. HAVENS, DONALD P. SMITH, MICHAEL S. BERGREN AND MARK A. LYSTER
Appeal No. 2001-0091
Application No. 08/732,254

NO DATE REFERENCE AVAILABLE FOR THIS DOCUMENT

BRUCE STEIN

PHARMACIA & UPJOHN COMPANY

INTELLECTUAL PROPERTY LEGAL SERVICES

301 HENRIETTA STREET

KALAMAZOO, MI 49001

Before WINTERS, ROBINSON, and GRIMES

Administrative Patent Judges

GRIMES

Administrative Patent Judge

ON BRIEF

DECISION ON APPEAL

An oral hearing in this case was scheduled for November 27, 2001. Upon reviewing the case, however, we have determined that an oral hearing will not be necessary and we render the following decision based on the record.

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1 and 2. Claims 1 and 2 are directed to specific crystal forms (form "S" and form "T," respectively) of 1-[5- Methanesulfonamidoindolyl-2-carbonyl]-4-[3-(1-methylethylamino)-2-pyridinyl]-piperazine. monomethanesulfonate salt. [FN1] The claims list the powder **X-ray diffraction** measurements that distinguish the claimed crystal forms from other forms of delavirdine mesylate.

The examiner relies on the following reference:

Palmer et al. (Palmer) 5,563,142 Oct. 8, 1996

Claims 1 and 2 stand rejected under 35 U.S.C. § 102(e) as anticipated by Palmer.

Claims 1 and 2 also stand rejected under 35 U.S.C. § 103 as obvious over Palmer.

Claims 1 and 2 also stand rejected for both statutory and obviousness-type double patenting, based on the claims of Palmer.

We reverse all of the rejections.

Discussion

The claims are directed to delavirdine mesylate in the S crystal form (claim 1) or in the T crystal form (claim 2). The examiner rejected the claims, under several different rationales, over the Palmer patent.

1. Statutory double patenting

The examiner rejected the claims under 35 U.S.C. § 101 "as claiming the same invention as that of claim 11 of prior U.S. Patent No. 5563142." Examiner's Answer, page 4. The examiner explained that "[i]n the absence of evidence showing otherwise, either of the instant claims may be the same compound recited in US'142." Id.

"35 U.S.C. § 101 prevents two patents from issuing on the same invention.... A good test, and probably the only objective test, for 'same invention,' is whether one of the claims could be literally infringed without literally infringing the other. If it could be, the claims do not define identically the same invention.... If it is determined that the same invention is being claimed twice, 35 U.S.C. § 101 forbids the grant of the second patent." In re Vogel, 422 F.2d 438, 441, 164 USPQ 619, 621-22 (CCPA 1970).

*2 Here, the patent's claim 11 is directed to delavirdine mesylate, without limitation as to crystal form. Instant claims 1 and 2 are directed to delavirdine mesylate in the S and T crystal forms, respectively. Thus, delavirdine mesylate in any crystal form other than S or T, or in a noncrystalline form, would infringe Palmer's claim 11 without infringing either of the claims on appeal. Therefore, the claims on appeal are not directed to the "same invention" as Palmer's claim 11 and are not unpatentable on that basis. The rejection under 35 U.S.C. § 101 is reversed.

2. Anticipation

The examiner rejected the claims under 35 U.S.C. § 102(e) on the basis that "Palmer discloses by name the same chemical compound as the mono methanesulfonate salt. See claim 11 in the US patent. In view of this fact evidence is needed that the prior art compound inherently lacks the characteristics (**x-ray diffraction** spectra recited in claims 1 and 2) relied on herein." Examiner's Answer, page 3.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "An inherent structure, composition or function is not necessarily known.... Insufficient prior understanding of the inherent properties of a known composition does not defeat a finding of anticipation." Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1349, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

"'Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."' In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981) (quoting Hansgirg v. Kemmer, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939)). When the inherent properties of a prior art product are at issue, "the examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner's belief that the functional limitation is an inherent characteristic of the prior art" before the burden is shifted to the applicant to disprove the inherency. Ex parte Skinner, 2 USPQ2d 1788, 1789 (Bd. Pat. App. Int. 1986).

Here, the claims on appeal are not directed to delavirdine mesylate per se, but are limited to the S and T crystal forms of that compound. Therefore, to anticipate the claims, the prior art must disclose delavirdine mesylate in the S and T crystal forms. The examiner has provided no evidence or scientific reasoning to show that the delavirdine mesylate disclosed and claimed by Palmer is in either the S or T crystal form. Therefore, the examiner has not made out a prima facie case of anticipation by inherency.

*3 The examiner's attempt to shift the burden of proof to Appellants was premature. The burden shifts to the applicant only if the examiner can show, by evidence or scientific reasoning, a reasonable basis for concluding that the prior art product meets all the limitations of the claims. The examiner has provided no basis for such a conclusion in this case. The rejection under 35 U.S.C. § 102 is reversed.

3. Obviousness

The examiner rejected the claims under 35 U.S.C. § 103 on the basis that Palmer "discloses the free form of the instant sulfonate salts for use in treating HIV." Examiner's Answer, page 3. The examiner concluded that the corresponding methanesulfonate salt would have been an obvious variant because Palmer "teaches and in fact prefers the use of salt forms for better solubility and crystallinity," and methanesulfonate salts were exemplified for compounds other than delavirdine mesylate. Id., pages 3-4.

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993).

The examiner's obviousness rejection seems to suffer the same infirmity as her anticipation rejection, namely, that it is directed to delavirdine mesylate per se, rather than to the specific S and T crystal forms of delavirdine mesylate that are the subject of the claims on appeal. The examiner has provided no evidence or convincing reasoning why the prior art disclosure of delavirdine mesylate in an undefined state would have suggested the specific S and T crystal forms that are the subject of the instant claims.

Nor has the examiner established that Palmer would have enabled those skilled in the art to make the claimed S and T crystal forms of delavirdine mesylate. Appellants' specification discloses specific conditions for recrystallizing delavirdine mesylate that produce the S and T crystal forms. See pages 2-4 and Examples 1-8. Palmer does not disclose or suggest even the existence of the S and T crystal forms of delavirdine mesylate, let alone how to make them. As stated in In re Hoeksema:

> [I]f the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public. In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on close relationships between their structures and those of prior art compounds.

*4 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968) (footnote omitted).

Since the examiner has not established that Palmer would have rendered the claimed invention obvious to those skilled in the art, she has not made out a prima facie case under 35 U.S.C. § 103. The rejection for obviousness is reversed.

4. Obviousness-type double patenting

The examiner rejected the claims for obviousness-type double patenting over Palmer's claim 11. The examiner argues that the instant claims and Palmer's claim 11 are not patentably distinct because they contain "overlapping subject matter" and because Palmer also claims the free form of delavirdine, which is an obvious variant of delavirdine mesylate. Examiner's Answer, page 4.

> Obviousness-type double patenting ... requires rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent. Its purpose is to prevent an unjustified extension of the term of the right to exclude granted by a patent by allowing a second patent claiming an obvious variant of the same invention to issue to the same owner later.

In re Berg, 140 F.3d 1428, 1431, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998) (citation omitted, emphasis added).

All proper double patenting rejections, of either type, rest on the fact that a patent has been issued and later issuance of a second patent will continue protection, beyond the date of expiration of the first patent, of the very same invention claimed therein (same invention type double patenting) or of a mere variation of that invention which would have been obvious to those of ordinary skill in the relevant art (obviousness-type double patenting). In the latter case, there must be some clear evidence to establish why the variation would have been obvious. In re Kaplan, 789 F.2d 1574, 1579-80, 229 USPQ 678, 683 (Fed. Cir. 1986) (emphasis in original).

Thus, a proper rejection for obviousness-type double patenting requires showing that the later-claimed subject matter "would have been obvious to those of ordinary skill in the relevant art" based on the claims in the earlier patent. As discussed above, the examiner has pointed to nothing in either the claims or the disclosure of the Palmer patent that would have suggested the S and T crystal forms of delavirdine mesylate to a person of ordinary skill in the art. We therefore reverse the rejection for obviousness-type double patenting.

Summary

We reverse all of the rejections because the examiner has not established that the prior art disclosed or suggested the claimed S and T crystal forms of delavirdine mesylate.

REVERSED

BOARD OF PATENT APPEALS AND INTERFERENCES

*5 SHERMAN D. WINTERS

Administrative Patent Judge

DOUGLAS W. ROBINSON

Administrative Patent Judge

ERIC GRIMES

Administrative Patent Judge

FN1. This compound is also known as delavirdine mesylate, Appeal Brief, page 2, and we will refer to it as such.

2003 WL 21279863 (Bd.Pat.App & Interf.)

END OF DOCUMENT

ATTACHMENT B

2002 WL 851814 (Bd.Pat.App & Interf.)
(Cite as: 2002 WL 851814 (Bd.Pat.App & Interf.))

Board of Patent Appeals and Interferences

Patent and Trademark Office (P.T.O.)
*1 EX PARTE DINESH GALA AND DONALD J. DIBENEDETTO
Appeal No. 2001-0987
Application 09/169,109

NO DATE REFERENCE AVAILABLE FOR THIS DOCUMENT

Thomas D. Hoffman

Schering-Plough Corporation

Patent Department K-6-1 1990

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Kenilworth NJ 07033-0530

Before WINTERS, WILLIAM F. SMITH, and ROBINSON

Administrative Patent Judges

Winters

Administrative Patent Judge

ON BRIEF

DECISION ON APPEAL

This appeal was taken from the examiner's decision rejecting claims 1 through 8, which are all of the claims pending in this application.

THE INVENTION

Applicants' invention relates to a crystalline "polymorph form 2 loratadine" having a specified x-ray powder diffraction pattern; a pharmaceutical composition comprising an anti-allergic effective amount of the polymorph form 2 loratadine and a pharmaceutically acceptable carrier; and a method of treating allergic reactions in a mammal by administering to the mammal an anti-allergic effective amount of polymorph form 2 loratadine. Claim 1, which is illustrative of the subject matter on appeal, reads as follows:

1. Polymorph form 2 loratadine having the following x-ray powder diffraction pattern expressed in terms of "d" spacing and relative intensities("RI").

d spacing (+-0.05)	RI
8.95	Weak
6.37	Weak
5.64	Weak

THE REFERENCES

The prior art references relied on by the examiner are:

Villani 4,282,233 Aug. 4, 1981

Sims et al. (Sims) WO 95/01792 Jan.19, 1995
(PCT Application)

THE REJECTIONS

Claims 1 through 8 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combined disclosures of Villani and Sims. Claims 1 through 8 further stand rejected under the judicially created doctrine of obviousness-type double patenting over claim 7 of Villani in view of Sims.

DELIBERATIONS

Our deliberations in this matter have included evaluation and review of the following materials: (1) the instant specification, including Figures 1 and 2, and all of the claims on appeal; (2) the Appeal Brief (Paper No. 10); (3) the Examiner's Answer (Paper No. 11); and (4) the above - cited prior art references.

On consideration of the record, including the above - listed materials, we reverse the examiner's rejections.

DISCUSSION

The question here is whether the combined disclosures of Villani and Sims support a conclusion of obviousness of claims 1 through 8, which recite the crystalline polymorph form 2 of loratadine having a unique x-ray powder diffraction pattern and infrared spectrum. We answer that question in the negative.

*2 Villani discloses polymorph form 1 of loratadine, but does not disclose or suggest that loratadine may assume distinct, crystalline polymorphic forms having different physical properties. Nor does Villani teach a person having ordinary skill in the art how to make polymorph form 2 of loratadine.

The Sims reference does not cure the deficiencies of Villani. Sims discloses a list of 16 non-sedating antihistamines, including loratadine, useful in combination therapy (Sims, page 8, lines 3 through 6). After listing those antihistamines, Sims refers to "a pharmaceutically acceptable salt, hydrate, or polymorph thereof" (id., lines 6 and 7). That reference to pharmaceutically acceptable salts, hydrates, or polymorphs, however, does not teach a person having ordinary skill in the art that loratadine may assume distinct, crystalline polymorphic forms having different physical properties. Rather, it appears that the above-quoted language constitutes boilerplate; and that Sims refers generally to pharmaceutically acceptable salts, hydrates, or polymorphs of any one of 16 non-sedating antihistamines without specifically suggesting that loratadine is capable of existing in the form of distinct crystalline polymorphs. On this point, we disagree with the examiner's finding that "Sims expressly teaches that loratadine may be in the form of polymorphs" (Examiner's Answer, page 3, lines 10 and 11). Nor does Sims teach a person having ordinary skill in the art how to make polymorph form 2 of loratadine.

On this record, applicants, and applicants alone, disclose that "loratadine can exist in the form of two distinct crystalline polymorphs, each having distinctly different physical properties" (Specification, page 2, first full paragraph). Applicants have discovered specific solvents and experimental conditions, producing a distinctly different polymorph form 2 of loratadine (Specification, page 3, last paragraph). Applicants discovered that crystallization of loratadine (prepared as described in U.S. Patent No. 4,282,233) from toluene, t-butylmethylether, heptane, or mixtures thereof, produce a polymorph form 2 loratadine. Applicants also discovered that using a t-butylmethylether-toluene mixture is preferred (Specification, page 4, second paragraph). This information stems from applicants' specification, but not from the cited prior art. Further, neither Villani nor Sims

discloses or renders obvious a method for making polymorph form 2 loratadine. As stated in In re Hoeksema, 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968),

> [I]f the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public. In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on close relationships between their structures and those of prior art compounds. [footnote omitted]

*3 The examiner relies heavily on this proposition of law set forth in Ex parte Hartop, 139 USPQ 525, 527 (Bd. Pat. App. 1962):

> [M]erely changing the form, purity or another characteristic of an old product, the utility remaining the same as that for the old product, does not render the claimed product patentable.

According to the examiner, polymorph form 2 loratadine is merely another form of an old product (polymorph form 1 loratadine) and both forms possess the same utility. Accordingly, the examiner concludes that applicants' claims, reciting polymorph form 2 loratadine, are unpatentable. We disagree. Here, we invite attention to In re Cofer, 354 F.2d 664, 667, 148 USPQ 268, 271 (CCPA 1966), where the court substantially discredited PTO reliance on the above-quoted proposition of law in Hartop. Like the situation presented in Cofer, the examiner in this case has not adequately established that the prior art (1) suggests the polymorph form 2 of loratadine; or (2) discloses or renders obvious a method for making the polymorph form 2 of loratadine.

Accordingly, the examiner's rejection of claims 1 through 8 under 35 U.S.C. § 103(a) as unpatentable over Villani in view of Sims is reversed. For essentially the same reasons, the rejection of claims 1 through 8 under the judicially created doctrine of obviousness-type double patenting over claim 7 of Villani in view of Sims is also reversed.

The examiner's decision rejecting claims 1 through 8 is reversed.

REVERSED

BOARD OF PATENT APPEALS AND INTERFERENCES

Sherman D. Winters

Administrative Patent Judge

William F. Smith

Administrative Patent Judge

Douglas W. Robinson

Administrative Patent Judge

2002 WL 851814 (Bd.Pat.App & Interf.)

END OF DOCUMENT

ATTACHMENT C

2002 WL 32334598 (Bd.Pat.App & Interf.)
(Cite as: 2002 WL 32334598 (Bd.Pat.App & Interf.))

*1 THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

Board of Patent Appeals and Interferences

Patent and Trademark Office (P.T.O.)
EX PARTE PETER MEISEL, KARL-FRIEDRICH LANDGRAF, JURGEN SCHAFER, WILFRIED THIEL, MATTHIAS RISCHER, ALFRED OLBRICH, AND BERNHARD KUTSCHER
Appeal No. 2002-0438
Application No. 09/181,671
Heard: October 10, 2002

VENABLE, BAETJER, HOWARD & CIVILETTI, LLP

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WASHINGTON, DC 20005-3917

Before WINTERS, SCHEINER, and GREEN

Administrative Patent Judges

GREEN

Administrative Patent Judge

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-3 and 16. Claim 1 is drawn to Modification A of the compound 2-amino-4-(4-fluorobenzylamino)-1-ethoxy-carbonylaminobenzene, wherein the modification is "characterized by the X-ray diffractogram, reflections not coinciding with the reflections of the other two modifications being observed, inter alia, at 6.97° 2<<THETA>> (12.67 Å), 18.02° 2<<THETA>> (4.92 Å) and 19.94° 2<<THETA>> (4.45 Å)." Claims 2 and 3 are drawn to Modification B and Modification C of the 2-amino-4-(4-fluorobenzylamino)-1-ethoxy-carbonylaminobenzene compound, each modification being defined by peaks appearing on the X-ray diffractogram. Claim 16 is drawn to pharmaceuticals "comprising the modification A, B or C" of the compound, "and, if appropriate, exipients and or auxiliaries." [FN1]

The examiner relies upon the following art:

German Patent Application
Dieter et al. (Dieter) DE 42 00 259 Jul. 15, 1993

Kirk-Othmer, "Crystallization," Encyclopedia of Chemical Technology, 4th Ed., Vol. 7, pp.700-702 (1993)

The claims stand rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Dieter and Kirk-Othmer. After careful consideration of the record and the issue before us, we reverse.

DISCUSSION

The Examiner's Answer rejects claims 1-3 and 16 as being obvious over the combination of Dieter and Kirk-Othmer. Dieter is cited for teaching the compound 2-amino-4-(4-fluorobenzylamino)-1-ethoxy-carbonylaminobenzene, as well as its use in

pharmaceutical compositions. Dieter does not discuss any possible crystal polymorphism of the disclosed compound.

Kirk-Othmer is cited for teaching that

> polymorphism is a condition in which a specific chemical compound may crystallize in different forms, that is, different space groups and with different physical and physico-chemical properties. An example is given of a simple compound, ammonium nitrate, with four form changes. In the paragraph which follows, it is stated that a specific **polymorph** may be absolutely essential for a particular crystalline product. By way of example, it is generally stated that one **polymorph** may have more desirable physico-chemical properties, i.e.[,] color, hardness, solubility or stability than another.

*2 Examiner's Answer, page 3.

The examiner notes that the instant claims are distinguishable over the prior art on the basis that it crystallized in three distinct crystalline forms, but states that "this does not render the compound in these crystalline forms patentable over the compound itself. The compound is neither new or novel, nor is its claimed use." Id. at 4. The rejection concludes that:

> It would have been obvious to one of ordinary skill in the art at the time of the invention that the three crystalline forms claimed by appellant[s] were intrinsic to the compound of the prior art, motivated by the fact that it is well known in the chemical arts that crystal polymorphism is a common and commonly recognized property of crystalline compounds.

Id.

Appellants argue that the examiner has failed to set forth a prima facie case of obviousness. Specifically, appellants argue that, at best, the combination teaches that the claimed compound may have polymorphisms that may be separable, thus the rejection fails to provide a reasonable expectation of success in arriving at the claimed invention. See Appeal Brief, page 6. We agree.

The burden is on the examiner to make a prima facie case of obviousness, and the examiner may meet this burden by demonstrating that the prior art would lead the ordinary artisan to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598-99 (Fed. Cir. 1988). The findings of fact underlying the obviousness rejection, as well as the conclusions of law, must be made in accordance with the Administrative Procedure Act, 5 U.S.C. § 706 (A), (E) (1994). See Zurko v. Dickinson, 527 U.S. 150, 158, 119 S.Ct. 1816, 1821, 50 USPQ2d 1930, 1934 (1999). Findings of fact underlying the obviousness rejection, upon review by the Court of Appeals for the Federal Circuit, must be supported by substantial evidence within the record. See In re Gartside, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). In addition, in order for meaningful appellate review to occur, the examiner must present a full and reasoned explanation of the rejection. See, e.g., In re Lee, 277 F.3d 1338, 1342, 61 USPQ2d 1430, 1432 (Fed. Cir. 2002).

The rejection of record does not meet the above criteria. Dieter, while teaching the compound that is the subject of the claims is known, does not teach or suggest that the compound has different crystalline structures. Thus, the rejection of record does not set forth any motivation to combine Dieter with Kirk-Othmer because, although Kirk-Othmer does teach that it is known that crystal polymorphism is known generally to exist, there is no teaching or suggestion in the references that the compound of the claimed invention is known to exhibit such polymorphism.

*3 Moreover, the record demonstrates that the compound as prepared by the prior art is a mixture of crystal **polymorphs**, whereas appellants have succeeded in isolating thee distinct **polymorphs**, i.e., Modifications A, B and C. See Declaration of Wilfried Thiel, Paper No. 9. Thus, the isolated crystal **polymorphs** as claimed in the instant application do not appear to be an inherent property of the claimed compound as disclosed by the prior art of record.

CONCLUSION

Because the rejection of record does not set forth a prima facie case of obviousness, it is reversed.

REVERSED

BOARD OF PATENT APPEALS AND INTERFERENCES

Sherman D. Winters

Administrative Patent Judge

Toni R. Scheiner

Administrative Patent Judge

Lora M. Green

Administrative Patent Judge

FN1. Note that the panel is interpreting this claim as requiring one of Modification A, Modification B or Modification C, but excluding mixtures of the disclosed modifications.

ATTACHMENT D

2003 WL 22282265 (Trademark Tr. & App. Bd.)
(Cite as: 2003 WL 22282265 (Trademark Tr. & App. Bd.))

*1 THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

Board of Patent Appeals and Interferences

Patent and Trademark Office (P.T.O.)
EX PARTE RICHARD P. POLNIASZEK, XUEBAO WANG, JEFFREY S. DEPUE, CHENNAGIRI R. PANDIT, YADAGIRI PENDRI, AND EDUARDO J. MARTINEZ
Appeal No. 2001-1805
Application No. 09/141,402

NO DATE REFERENCE AVAILABLE FOR THIS DOCUMENT

MARLA J MATHIAS

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PATENT DEPARTMENT

PO BOX 4000

PRINCETON NJ 08543-4000

Before WINTERS, SCHEINER, and ADAMS

Administrative Patent Judges

ADAMS

Administrative Patent Judge

ON BRIEF

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claim 41, which is the only claim pending in the application and is reproduced below:

41. A high melt **polymorph** of the compound N-(3,4-dimethyl-5-isoxazolyl)-4'- (2-oxazolyl)[1,1'-biphenyl]-2-sulfonamide, which has a melting point of approximately 143.07 to 145.1° C.

The examiner relies on:

Murugesan 5,612,359 Mar. 18, 1997

GROUND OF REJECTION

Claim 41 stands rejected under 35 U.S.C. § 103 as obvious over Murugesan.

DISCUSSION

At the outset, we wish to make it clear that "reliance on per se rules of obviousness is legally incorrect" and must stop. In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). Accord, In re Brouwer, 77 F.3d 422, 425, 37 USPQ2d 1663, 1666 (Fed. Cir. 1996).

A per se approach would be in conflict with long standing precedent as to the relevance of the method of making a product to the obviousness of the product. Note In re Payne, ("[a]n invention is not 'possessed' absent some known or obvious way to make it.") citing In re Hoeksema, 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968). In a similar manner, the court in In re O'Farrell, 853 F.2d 902, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988), in considering the Polisky reference relative to the rejected claims stated "Polisky contained detailed enabling methodology for practicing the claimed invention, a suggestion to modify the prior art to practice the claimed invention, and evidence suggesting that it would be successful." (Emphasis added). See also, In re Lalu, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1984)("[t]he prior art must provide one of ordinary skill in the art the motivation to make the proposed molecular modifications needed to arrive at the claimed compounds.")

*2 Since there are no per se rules of obviousness or nonobviousness, each case must be decided upon the facts in evidence in that case. See In re Cofer, 354 F.2d 664, 667, 148 USPQ 268, 271 (CCPA 1966) ("[n]ecessarily it is facts appearing in the record, rather than prior decisions in and of themselves, which must support the legal conclusion of obviousness under 35 U.S.C. § 103"); and Ex parte Goldgaber, 41 USPQ2d 1172, 1176 (Bd. Pat. App. & Int. 1995)("each case under 35 U.S.C. § 103 is decided on its own particular facts.").

We find the examiner's argument (Answer, page 4), "[t]he Court [in] In re Cofer expands upon rather than rejects what the Appellants term a 'purported [per se] rule"' legally flawed and in error. As set forth supra, our appellate reviewing court has made it clear that there are no per se rules of obviousness.

As a second error, we find that the examiner failed to provide any rationale or analysis to support her position in either the Answer or the Final Rejection. For emphasis we reproduce in full the examiner's statement of the rejection from page 3 of the Answer -- "Claim 41 is rejected under 35 U.S.C. [§] 103(a) as being unpatentable over ... Murugesan." In this regard, we suggest the examiner review the Manual of Patent Examining Practice (MPEP) § 706.02(j) for a model of how to explain a rejection under this section of the statute. Furthermore, we direct the examiner's attention to MPEP § 1208, "[a]n examiner's answer should not refer, either directly or indirectly, to more than one prior Office action." In this instance the Answer neither provides a reasoned explanation of the rejection, nor does it direct our attention to any prior Office action where a reasoned analysis of the facts is provided.

Contrary to the examiner's position (Answer page 5) [FN1], we find the N-(3,4-Dimethyl-5-isoxazolyl)-4'-(2-oxazolyl)[1,1'-biphenyl]-2-sulfonamide compound set forth in Example 1(D) of Murugesan to be the most relevant compound to appellants' claimed invention. However, as appellants point out (Brief, page 4) Murugesan "discloses an amorphous form of this compound, having a melting point of 90 to 98° C....." Stated differently, notwithstanding that the claimed compound has the same formula as Murugesan, the examiner has not established that Murugesan suggests appellants' specifically claimed **polymorph**. This is clearly demonstrated by the different melting points for the two compounds.

We note the examiner's analysis of the N-(3,4-Dimethyl-5-isoxazolyl)-4'-(5-oxazolyl)[1,1'-biphenyl]-2-Sulfonamide compound set forth in Murugensan's example 4, wherein she states (Answer, page 6) that a "difference in bonding location would result, as expected in any isomeric situation, in certain differences in physical properties. Here, one such difference is reflected in melting points that range from 189-191° C[] for the Murugesan compound compared to 143-145° C[] for the instantly claimed compound." However, the problem with this argument should be self evident (Answer, page 6), the "compound taught by Murugesan differs from the instantly claimed compound ... at the 5-oxazolyl position...." As appellants argue (Reply Brief, page 2), "[w]hile Example 4 of ... [Murugesan] indeed discloses a crystalline form of a compound having a melting point of 189-191° C, it fails to disclose or suggest the invention of claim 41 ... having a melting point of approximately 143-145° C." Stated another way, they are different compounds.

*3 The claimed invention is drawn to a specific polymorphic form of N-(3,4-

Dimethyl-5-isoxazolyl)-4'-(2-oxazolyl)[1,1'-biphenyl]-2-sulfonamide that has a melting point of approximately 143-145° C. The prior art relied upon by the examiner does not teach this specific **polymorph** as claimed by appellants. The examiner failed to demonstrate that the prior art even recognized that the claimed compound exists in different polymorphic forms, or that there is a known or obvious way to manufacture the specific polymorphic form claimed. Hoeksema. Stated differently, the examiner failed to demonstrate that Murugesan provides an enabling disclosure of the compound set forth in appellants' claim 41. In contrast the examiner has not rejected appellants' claims under 35 U.S.C. § 112, first paragraph, thus the examiner has found on this record that appellants' specification provides an enabling disclosure of how to make and use the claimed invention.

For the foregoing reasons we reverse the rejection of claim 41 under 35 U.S.C. § 103 over Murugesan.

REVERSED

BOARD OF PATENT APPEALS AND INTERFERENCES

Sherman D. Winters

Administrative Patent Judge

Toni R. Scheiner

Administrative Patent Judge

Donald E. Adams

Administrative Patent Judge

FN1. At page 5 of the Answer, the examiner finds that "[e]xample 4 of Murugesan is believed to be the most relevant and most critical to the issue of obviousness for the instant application.".